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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/830,652	04/30/2001	Akihiro Kondo	KONDO 7	1863

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BROWDY AND NEIMARK, P.L.L.C.
624 NINTH STREET, NW
SUITE 300
WASHINGTON, DC 20001-5303

EXAMINER

CHUNDURU, SURYAPRABHA

ART UNIT	PAPER NUMBER
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1637

DATE MAILED: 09/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/830,652

Applicant(s)

KONDO ET AL.

Examiner

Suryaprabha Chunduru

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 May 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13 and 14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13 and 14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. Applicants' response to the office action and amendment filed on May 18, 2004 has been entered.
2. Claims 1-12 are cancelled. claims 13-14 are pending in this application.
3. This application filed on April 30, 2001 is a 371 of PCT/JP99/05964 filed on October 28, 1999.

New Grounds of Rejections necessitated by Amendment

3. Claim 13 is objected because of the following informalities:

(i) in step (c) typographic errors

'probe' typed as prove;

'in' typed as 'inn'.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 13 recites the limitation "the gene" in step (c). There is insufficient antecedent basis for this limitation in the claim. The instant claim recites in step (c), 'hybridizing a first probe and a second probe with genes' and relate the DNA fragments from "the gene". The term "the gene" lacks support in the claim because the claims refers to plurality of genes and " the gene" lacks antecedent basis.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 13 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wang et al. (Biochem. Biophys. Res. Commun., Vol. 220, pp. 784-788, 1996) in view of Schena (Proc.Natl. Acad. Sci. USA., Vol. 93, pp 10614-10619, 1996).

Wang et al. teach a method of claims 13 and 14, for determining a signal transduction pathway gene expression, that is influenced by an endocrine disrupting activity of a test substance (dioxin) comprising

(a) exposing a cell to a test substance (TCDD dissolved in DMSO) (see page 785, paragraph 1 under experimental procedures section);

(b) isolating a first mRNA from the cell that has been exposed to the test substance (see page 785, paragraph 1 under experimental procedures section) and a second mRNA from a cell that has not been exposed to the test substance (only DMSO) (see page 785, paragraph 1 under experimental procedures section, line 1-2 of paragraph 1 under results and discussion section);

(c) hybridizing the mRNAs (first and second probes) with DNA fragments (labeled probes in an array (mRNAs immobilized on nylon membrane) (see paragraph 7 under experimental procedures section);

(d, e) comparing and identifying a series of genes in which the expression levels are altered as a result of exposure of cell to the test compound (see page 787, Fig. 2, paragraph 2, where four TCDD-responsive genes are identified).

However, Wang did not specifically teach the genes on the DNA array comprising at least one gene for each of the respective groups 1 to 17 of step (f).

Schena et al. teach a microarray-based gene expression monitoring of whole human genome comprising about 1000 genes on an array (see page 10614, abstract, col. 2, paragraphs 1-3); comparing and determining the signals using fluorescence imaging system (see page 10615, col. 1, paragraph 4, Fig. 1).

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made, to modify a method for identifying endocrine disruptor activity of a test substance as taught by Wang et al. with a method of identifying genes in whole human genome which includes genes related to signal transduction pathway as taught by Schena et al. to achieve expected advantage of developing a an improved and sensitive molecular diagnostic method for gene targeting because Schena et al. states that “the parallel gene analysis with microarrays provide a rapid and efficient method for large-scale human gene discovery and facilitate insights into growth, development, differentiation, homeostasis, aging, and onset of diseases (see page 10614, abstract, col. 1, paragraph 1). An ordinary practitioner would have been motivated to modify the method of identifying endocrine-disrupting activity of a test substance as taught by Wang et al. with the incorporation of the determining a series of genes related to growth, development, differentiation and homeostasis which include signal transduction pathway genes as taught by Schena et al., which would improve the characterization of a test substance and facilitate in a better screening of a wide variety of test substances based on monitoring gene expression in a high-throughput assay.

Response to Arguments

6. Applicants' response to the office action is fully considered and found persuasive.

7. With reference to the rejection made in the previous office action under 35 USC 112, second paragraph, Applicants' amendment is fully considered and found persuasive. The rejection is withdrawn herein in view of the amendment.

8. With reference to the rejection made in the previous office action under 35 USC 103(a) Applicants' arguments and amendment are fully considered and found persuasive. The rejection is withdrawn herein in view of the amendment, arguments and new grounds of rejection.

Conclusion

No claims are allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 571-272-0783. The examiner can normally be reached on 8.30A.M. - 4.30P.M, Mon - Friday.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782 . The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and - for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


Suryaprabha Chunduru
September 1, 2004


JEFFREY FREDMAN
PRIMARY EXAMINER

9/2/04